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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,853	02/09/2007	Gen-Ichiro Soma	80246(302741)	9265

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EXAMINER	
MI, QIUWEN	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,853	SOMA ET AL.	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-14,16-22,26-29 and 33-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-14,16-22,26-29 and 33-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/29/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

CONTINUED EXAMINATIONS

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/29/09 has been entered.

Applicant's reply filed on 11/30/09 is acknowledged. Claims 1-11, 15, 23-25, and 30-32 are cancelled. Claims 12-14, 16-22, 26-29, and 33-38 are pending. **Claims 12-14, 16-22, 26-29, and 33-38 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

Claim Rejections –35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-14, 16-22, 26-29, and 33-38 remain rejected under 35 USC § 102 (b) as being anticipated by Soma et al (US 5,494,819), as evidenced by Inagawa et al (Homeostasis as regulated by activated macrophage. II. LPS of plant origin other than wheat flour and their concomitant bacteria, Chem. Pharm. Bull. 40 (4) 994-997, 1992)*.

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 9/29/09, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Soma et al teach three glucose-fermentative gram-negative small bacilli which produce lipopolysaccharide (LPSs) (col1, lines 12-15). The three bacterial according to the present invention were isolated from all kinds of wheat produced in any place and its processed goods (col 3, lines 10-16). Soma et al also teach in a 50 ml coning tube, there was charged 1.04 g of hard flour containing 1.09% of ash followed by addition of 20 ml of distilled water therto to prepare a 50 mg/ml aqueous solution of wheat flour (thus a fermented edible plant extract). The solution was cultured in a water bath at 37°C for 0, 1, 2, 3, 4, 6, 8, 10, 12, 20, 24, and 45 hours (col 5, lines 46-55) (thus fermented, thus contains no component derived from an animal). Soma et al also teach the colony formation from and isolation of *Pantoea agglomerans* from aqueous solution of wheat flour (throughout the document). Thus the pure culture *Pantoea agglomerans* is the fermented extract from edible plant wheat, and therefore the fermented plant extract. Soma et al further teach a pure culture of *Pantoea agglomerans* (thus facultative anaerobic gram-negative bacterium, bacillus) which produces lipopolysaccharides (col 1, 7-13), and it may be used in food (thus a food containing the fermented plant extract, thus the limitation of claims 18 and 21 is met), drinks and feed (col 5, lines 10-15), it has excellent immunity-stimulating (thus the fermented plant extract has an immunopotentiation activity, thus the limitation of claim 17 is met), analgesic and antiwithdrawal effects show a high therapeutical range, and may be provided at a low cost and in a large amount (col 2, lines 50-55). At last, Soma et al teach any of the above preparations (thus a pharmaceutical, thus the limitation of claim 14 and 20 is met) including

immunity stimulators may be produced conventionally. For example, in the conventional manner of preparing medicines (thus a composition, a pharmaceutical) or veterinary medicines, they may be supplied conventionally in the form of powders (thus a fermented plant extract powder, thus the limitation of claims 13,27, 34, 36, and 38 is met), granules, pills, tablets, troches, capsules, solutions, pastes, ointments, liniments, lotions (thus a bath agent containing the fermented plant extract, thus the limitation of claims 19 and 22 is met), suppositories, injections, etc (col 5, lines 12-18).

As evidenced by Inagawa et al, lipopolysaccharide (LPS) of plant origin other than that of wheat four was surveyed. Concomitant bacteria possibly extracting in root of farm products can be considered to contribute of LPS of plant origin. Some LPS were derived from concomitant bacteria which had probably come from root. Three predominant bacteria have been isolated and identified; Pantoea agglomerans, Enterobacter cloacae and Serratia ficaria. These LPSs were purified and their chemical compositions were examined (see Abstract). Pantoea agglomerans is the most remarkable, since it accounts for 40-70% of all living bacteria in wheat bran and wheat flour and is persistently isolated from all kinds of wheat four produced in districts as different as, Canada, USA, Australia and Japan (page 996, 2nd column, last column). Inagawa et al also teach, Pantoea agglomerans is a species of gram-negative soil bacterial ubiquitously distributed, especially in cotton-seed and wheat, and contributes to the growth of plant by nitrogen fixation and also by release of phosphorus (page 997, 1st column, 1st paragraph) (thus lives in a symbiotic relationship exclusively with a plant).

Therefore, the aqueous solution of wheat flour culture in Soma et al inherently contains the symbiotic gram-negative soil bacterial Pantoea agglomerans, and "facultative anerobic" is the intrinsic properties of the bacteria.

It is noted that since the cited reference teaches the claimed fermented plant extract, it is deemed that the fermented plant extract would inherently have macrophage activation ability even with the presence of polymyxin B (thus the limitation of claim 16 is met).

Therefore, the reference is deemed to anticipate the instant claim above.

*This reference is cited merely to relay an intrinsic property and is not used in the basis for rejection *per se.*

Applicant argues that "The applicant respectfully rebuts the rejection over Soma and Inagawa by showing that fermentation cannot biologically occur according to the disclosure of these two references" (page 2, 3rd paragraph). Applicant states that "In Soma, the sentence "The solution was cultured" (col. 5, line 53) is technically wrong, because any solution must not be cultured. Since the sentence should read, "The solution was shaken" (the original Japanese sentence intends this) or "Bacteria were cultured," it is apparent that the sentence is an erroneous translation. (Scientists sometimes describe "to culture" as a generalized expression when he/she considers using a concussion (shaking) incubator. Even if he/she uses inanimate being, he/she can describe it as "to culture.") In this case he/she means "to concuss" or "to shake" when using the generalized term "to culture."(page 2, 4th paragraph) Applicant also argues that "In the case of Soma, since the Example 1 solution contains only "Canadian wheat" (col. 5, line 49) and "distilled water" (col.5, line 50), the *solution is, in fact, too oligotrophic to culture bacteria* even

if it is in a water bath at 37°C. It is easy for a person who knows wheat flour to understand "50 mg/ml aqueous solution of wheat flour" (col. 5, lines 51-52) cannot culture bacteria. It is well known that simple wheat flour and water will not culture. Thus Soma cannot be interpreted as teaching culturing, when in fact a culture cannot biologically occur" (page 2, 5th paragraph). Applicant further argues that "Generally, one needs to isolate the bacterium from the "Bacteria-providing sources" (col. 3, line 10) before culturing the bacterium. The process, *"(T)he solution was cultured in a water* ***bath*** at 37°C while shaking," (col. 5, lines 53-54) is" to isolate **the bacteria from wheat four (col. 3, lines 16-19). And the isolated bacteria are cultured in "standard agar culture media** available from Nissui Seiyaku Co. in Japan" (col. 5, lines 57-58) to determine the number of living cells and to observe the colonies. The standard agar culture media, which culture the bacteria, contain "Peptone" (in the table in col. 5, line 65) and the *Peptone is* ***animal protein.*** Only under proper minimum conditions will the culture biologically occur" (page 2, last paragraph). Applicant argues that "Therefore as shown above, Soma fails to disclose "culturing ... bacterium in a medium containing no component derived from an animal" (the present claims 12, 26 and 33) because the ***actual culturing in Soma occurs with animal components'.*** Inagawa does not compensate for the deficiency in Soma described above. Applicant further argues that "Further, it is apparent that the process is not culturing because the colonies are observed only at 8 hours and 10 hours in 0 to 45 hours and it means that the bacteria did not grow proliferously" (page 2, 6th paragraph). Applicant argues that "Furthermore, it is apparent that the process is not culturing because observation of colonies is tried even at 0 hour" (page 2, 7th paragraph).

This is not found persuasive. First of all, Soma et al explicitly teach "The solution was cultured in a water bath at 37°C for 0, 1, 2, 3, 4, 6, 8, 10, 12, 20, 24, and 45 hours". Secondly, bacteria could be cultured at 37°C water bath while shaking, and Applicant's understanding of culture as agar culture is very narrow. Thirdly, there is enough nutrients in wheat flour for bacteria to grow. The fact that colonies are observed at 8 hours and 10 hours proves that the solution shaken in a water bath at 37°C did form bacteria. In addition, every experiment should have a 0 hour control, and it is a common knowledge. Further more, the wheat flour solution does not contain any animal protein.

Thus, the reference is deemed to anticipate the instant claims.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Examiner, Art Unit 1655